K072368 1/3

## SECTION 2

SEP 20 2007

# 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of the 510(k) premarket notification for the ConforMIS, Inc. Unicondylar Knee Repair System is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

## Summary of Safety and Effectiveness

**Submitted By:** ConforMIS, Inc.
2 Fourth Avenue
Burlington, MA 01803

**Contact Person:** S. Michael Sharp, PhD
Sr. Vice President, Regulatory/Clinical & Quality

**Date:** August 22, 2007

**Trade/Proprietary Name** Metal Backed Tibial Component ("mBT")

**Common Name** Metal-backed tibial component

**Reference/Classification Name** 21 CFR 888.3520 – Knee joint femorotibial metal/polymer non-constrained cemented prosthesis

**Predicate Devices**

| Technological Characteristics | Design & Insert Thickness | Indications for Use |
|---|---|---|
| ConforMIS UniCondylar Knee Repair System (K043570) | DePuy Preservation Unicondylar Knee (K040268) | ConforMIS UniCondylar Knee Repair System (K043570) |
| ConforMIS BiCompartmental Knee Repair System (K053488) | ConforMIS Metal-backed Tibial Component ("mBT") (K063432) | ConforMIS BiCompartmental Knee Repair System (K053488) |
| | DePuy Preservation Unicondylar Knee (K040268) | DePuy Preservation Unicondylar Knee (K040268) |
| | Encore Uni Knee (K022437) | |
| | Whiteside Biomechanics Unicompartmental Knee System (K01280 | |

**Intended Use:**

The ConforMIS metal backed tibial component is intended for use with the ConforMIS Unicondylar Knee Repair System and the ConforMIS BiCompartmental Knee Repair Systems, in patients with:

- joint impairment due to osteoarthritis or traumatic arthritis of the knee
- previous tibial condyle or plateau fracture, creating loss of function
- valgus or varus deformity of the knee

The ConforMIS metal backed tibial component is intended only for use with bone cement

**Device Description**

The ConforMIS Metal Backed Tibial Component is to be used with either the ConforMIS Unicondylar Knee Repair System or the ConforMIS BiCompartmental Knee Repair System to provide the surgeon with an alternative tibial component in the event that he/she prefers to use a metal backed component rather than an all polyethylene component. It consists of a cobalt-chrome alloy (CoCrMo) tray and a polyethylene insert. The X/Y dimensions of the device (i.e. the two-dimensional shape or "footprint") are designed to conform to the patient's anatomy as closely as possible based on images (MRI or CT scan) of the patient's knee. It is available with UHMEPE inserts with minimal thickness from 6 to 14 mm.

**Comparison to Predicates**

The ConforMIS Metal Backed Tibial Component is substantially equivalent to the tibial components cleared for the ConforMIS Unicondylar and BiCompartmental Knee Repair Systems in is use of imaging data to design a patient-matched implant geometry, as well in terms of design and production process, as well as materials and indications. It is substantially equivalent to the cited predicate devices in terms of design, materials, mechanical safety and intended use. All are intended for cemented use only.

**Performance Data**

Non-clinical Performance and Conclusions:
Testing completed as part of the design verification procedure for the ConforMIS Metal

Backed Tibial Component found this device to be as safe and effective as the predicate devices, further confirming substantial equivalence.

Clinical Performance:
Clinical data and conclusions are not necessary to demonstrate substantial equivalence.

## SUMMARY

Based on the similarities in design, materials, function, and intended use the ConforMIS Metal Backed Tibial Component is substantially equivalent to the devices currently marketed under the Federal Food, Drug and Cosmetic Act. In addition, the ConforMIS Metal Backed Tibial Component raises no new safety or effectiveness issues.

## USE OF THE TERM "SUBSTANTIAL EQUIVALENCE"

The term "Substantial Equivalence" is used in this submission within the confines of the statutory use in the FDA's evaluation of a Pre-Market Notification Submission. Any statement regarding Substantial Equivalence used in this submission relates only to whether the device that is the subject of this submission may be lawfully marketed in the United States without pre-market approval or reclassification, and should not be interpreted as an admission, or any kind or type of evidence, in any patent proceeding, including patent infringement litigation or proceeding before any Patent Office.

The present submission and statements therefore should not be construed as affecting or relating to the scope of any patent or patent application, or to whether the product addressed in the submission, or its use, may be considered indistinct, from a patentability perspective, from any other device referred to in this sub mission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

ConforMIS, Inc.
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2 Fourth Avenue
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SEP 2 0 2007

Re: K072368
Trade/Device Name: Metal Backed Tibial Component
Regulation Number: 21 CFR 888.3520
Regulation Name: Knee joint femorotibial metal/polymer non-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: HSX
Dated: August 22, 2007
Received: August 23, 2007

Dear Dr. Sharp:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Melkerson for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K072368

Device Name: ConforMIS Metal Backed Tibial Component (mBT)

Indications For Use:

The ConforMIS metal backed tibial component is intended for use with the ConforMIS Unicondylar Knee Repair System and the ConforMIS BiCompartmental Knee repair Systems, in patients with:

- joint impairment due to osteoarthritis or traumatic arthritis of the knee
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- valgus or varus deformity of the knee

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Ruehl MD

**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**



**510(k) Number** K072368